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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO 16-MD-2738 (FLW) (LHG)

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IN RE JOHNSON & JOHNSON : DAUBERT HEARING
POWDER PRODUCTS MARKETING, : JULY 30, 2019
SALES PRACTICES. : VOLUME 7
----- :

CLARKSON S. FISHER UNITED STATES COURTHOUSE
402 EAST STATE STREET, TRENTON, NJ 08608

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(Continued.)

* * * * *
VINCENT RUSSONIELLO, RPR, CRR, CCR
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1 your articles discuss your theory talcum powder causes
2 ovarian cancer. True?

3 A. That's right, because that's not the intent of
4 any of those articles.

5 Q. You would agree with me, Dr. Clarke-Pearson, and
6 I heard you mention it this morning, that the
7 potential association between talcum powder and
8 ovarian cancer has been reported in the literature for
9 decades. Correct?

10 A. That information has been gathering over time.

11 Q. And, in fact, at your deposition you told us
12 that you yourself have been aware of the potential
13 association since your residency back in 1975.
14 Correct?

15 A. That's true.

16 Q. But the truth is, Dr. Clarke-Pearson, that it
17 wasn't until the end of 2018, after you were hired by
18 the plaintiffs' lawyers, that you formed the opinion
19 that talcum powder causes ovarian cancer. True?

20 A. No. I formed my opinion before I was hired by
21 the lawyers.

22 MS. BROWN: Permission to read, your Honor.

23 THE COURT: Yes.

24 Q. At your February 4th, 2019, deposition, page
25 104, lines 3 through 24, you were asked -- talking

1 about a video that we will talking about in a little
2 bit:

3 "You did not tell the viewers that talcum
4 powder was associated with a cause of ovarian cancer.
5 Is that right?

6 "ANSWER: That's correct. Because at that
7 point in time I didn't believe it was causative.

8 "QUESTION: It wasn't until after being
9 retained in this case and around the time that you
10 concluded your review in November of 2018, that you
11 formed that opinion."

12 There was an objection.

13 "ANSWER: As I was preparing to offer an
14 opinion I did this review and came to that opinion,
15 yes.

16 "QUESTION: If we try to put a time on it, it
17 would be toward the latter part of 2018, once you had
18 completed your review that you told us about in
19 connection with this litigation. Correct?

20 "ANSWER: Yes."

21 I want Dr. Clarke-Pearson --

22 A. Can you tell me when the video you are
23 referencing the very time is?

24 Q. I'll ask you some questions about it. We're
25 going to get to it. Right now I want to talk about

1 some other publications you had in your field over the
2 years.

3 In 1993 you authored a publication regarding
4 mutations of the p53 gene and ovarian cancer. Do you
5 recall that?

6 A. Not really. I was a co-author and that was a
7 long time ago. Do you have that in the exhibits?

8 Q. Absolutely. You were asked about this paper at
9 your deposition a few months ago. Do you recall that?

10 A. I do.

11 Q. You can find it in your binder up there,
12 Dr. Clarke-Pearson, at tab 501. We'll also bring it
13 up on the screen to aid you.

14 Do you recall, Dr. Clarke-Pearson, talking
15 about this article a few months ago in your deposition
16 and --

17 A. I'm not listening to you while I'm trying to
18 find this.

19 MS. BROWN: May I approach to help him?

20 THE COURT: Yes.

21 (Pause.)

22 Q. Have you got that in front of you?

23 A. Yes.

24 Q. This was an article you were a co-author on back
25 in 1993 regarding the p53 gene in ovarian cancer.

1 Correct?

2 A. Correct.

3 Q. And one of the things that you note in this
4 article is that approximately one-half of human
5 epithelial ovarian cancers have mutations in the p53
6 gene. Correct?

7 A. That's what we found.

8 Q. And what you concluded in this article with your
9 co-authors back in 1993 is that "p53 mutations in
10 ovarian cancer arise because of spontaneous errors in
11 DNA synthesis and repair rather than a direct
12 interaction of carcinogens with DNA. These molecular
13 data you and your co-authors noted here in your
14 article, these molecular data are consistent with data
15 from epidemiologic studies that have failed to
16 demonstrate a convincing relationship between exposure
17 to environmental carcinogens and the development of
18 ovarian cancer."

19 That's what you wrote in 1993. Correct?

20 A. That's what my lead author wrote and I was a
21 co-author, yes.

22 Q. Doctor, just to orient us as we walk through
23 your field and testimony, you told us a moment ago you
24 first became aware of the potential association of
25 talc and ovarian cancer during your residency in 1975.

1 True?

2 A. That's right, based on Johns Hopkins data from
3 Woodruff and Parmley.

4 Q. We just looked at an article from 1993 which you
5 were a co-author on in which you concluded that most
6 environmental carcinogens are not linked to p53
7 mutations. Right?

8 A. That's what that article said, yes.

9 Q. I want to take a look at another article that
10 you wrote, Dr. Clarke-Pearson, in 2009, and you can
11 find that in the very next tab in the binder in front
12 of you at 502. This is an article -- if we can bring
13 it up on the screen -- that you were in fact the sole
14 author of. Correct?

15 A. This is an invited review article from the New
16 England Journal, and I was the sole author, yes.

17 Q. And the New England Journal of Medicine we can
18 agree is a prestigious medical journal. Correct?

19 A. I said that earlier, yes.

20 Q. The article here is entitled, "Screening For
21 Ovarian Cancer." Correct?

22 A. Yes.

23 Q. One of the things you were telling us earlier
24 today is that by the time you treat patients, they in
25 many cases already have ovarian cancer. Correct?

1 A. Yes.

2 Q. But part of your research and the focus of your
3 40 years in this area has also been on how to screen
4 women for ovarian cancer and how to prevent women from
5 getting ovarian cancer. Correct?

6 A. Yes.

7 Q. And in this particular article you posed a
8 hypothetical -- you were posed a hypothetical at the
9 beginning, and the article deals with circumstances in
10 which a physician should consider screening a woman
11 for ovarian cancer. Correct?

12 A. No. It is not intended -- the article concludes
13 that we are not able to screen for ovarian cancer. So
14 I was not encouraging physicians to screen for ovarian
15 cancer because there was no mechanism in 2009 or in
16 2019 on how we can screen for ovarian cancer.

17 Q. I'm not trying to quibble with you on this.

18 A. I'm just stating what this article is intended
19 to say.

20 Q. Let's see if we can understand each other, what
21 this article is about.

22 The article starts out with a description of a
23 putative plaintiff who has come to her physician with
24 this description. Fair enough?

25 A. That's the case.

1 Q. And you review throughout the article the state
2 of knowledge of ovarian cancer, and you include a
3 discussion of some risk factors for ovarian cancer.
4 Correct?

5 A. Some risk factors.

6 Q. And your ultimate conclusion in this article is
7 this woman should not be screened for ovarian cancer.
8 Correct?

9 A. Because we don't have any screening methods to
10 use. So why would we screen.

11 Q. That's unfortunately one of the terrible things
12 about ovarian cancer is that we don't have a way to
13 screen women for ovarian cancer. Correct?

14 A. That's correct.

15 Q. And what you note in connection with this
16 article, Doctor, is you comment on that very thing.
17 And if we could look at page 2, second column, top
18 paragraph, one of the things you are talking about is
19 that because there is no obvious precursor lesion,
20 screening has to focus on early detection of invasive
21 cancer. Correct?

22 A. Where does it say "early detection"?

23 Q. Very top. Because there is no obvious precursor
24 lesion. Are you with me?

25 A. Yes. That wasn't highlighted.

1 Q. "Screening must focus on early detection of
2 invasive cancer." Correct?

3 A. That's the whole idea of any screening for
4 cancer.

5 Q. What you go on to state in this 2009 article in
6 the prestigious New England Journal of Medicine is
7 that risk factors other than age, a family history of
8 ovarian or breast cancer, and the presence of a BRCA
9 mutation are poorly understood, and approximately 90
10 percent of ovarian cancers appear to be sporadic.
11 Correct?

12 A. Yes.

13 Q. In this 2019 article, 2009 article in the New
14 England Journal of Medicine, you made no reference to
15 talc as a causative agent or a risk factor for ovarian
16 cancer. True?

17 A. There are a number of other risk factors that we
18 didn't include in that study because, again, you can't
19 screen for ovarian cancer.

20 Q. In your 2009 article in the New England Journal
21 of Medicine you make no reference to talc as a
22 causative agent in ovarian cancer. Is that correct,
23 Doctor?

24 A. I didn't make the reference to that or didn't
25 make the reference to incessant ovulation,

1 endometriosis, pelvic inflammatory disease, for
2 example.

3 Q. In fact, what you did is you called out three
4 risk factors, right? Age, family history, and BRCA
5 mutation. Correct?

6 A. Yes.

7 Q. And for the others you wrote that they are
8 poorly understood. Correct?

9 A. Yes.

10 Q. In 2011, Dr. Clarke-Pearson, you did some work
11 with the Society of Gynecologic Oncologists as you
12 have over the course of your career. Correct?

13 A. Yes.

14 Q. And you were part of a publication which can be
15 found at 530 in your binder -- and if we could bring
16 that up -- called "Pathways to Progress in Women's
17 Cancer, a Research Agenda Proposed by the Society of
18 Gynecologic Oncologists."

19 Just to orient us, Dr. Clarke-Pearson, you
20 have held some leadership positions in that
21 organization, including being the president. True?

22 A. Correct.

23 Q. And in this particular publication, Pathways to
24 Progress from 2011, your name appears here on the
25 first page as the immediate past president of this

1 Society. Correct?

2 A. Yes, as a cover letter to the membership.

3 Q. If we could look at the first paragraph of the
4 cover letter to this publication, you and the then
5 president write in the third sentence, you give a
6 little context for what this report is in fact about,
7 and you say:

8 "To make our vision a reality, SGO has in this
9 research report entitled, Pathway to Progress In
10 Women's Cancers, identified and outlined the areas of
11 research by diseases upon which the women's cancer
12 community should focus for the next decade."

13 Do you see that, Doctor?

14 A. Yes.

15 Q. So part of this publication, what this was to
16 progress in women's cancer was to identify areas of
17 research and to improve research and study in the
18 field of gynecologic cancers. True?

19 A. Certainly, that's what we want to do.

20 Q. And on page 17 of this document, Doctor, one of
21 the things that you write about is similar to what we
22 have been talking about, the idea that screening for
23 ovarian cancer is notoriously difficult. Correct?

24 A. Yes.

25 Q. And you have a section in this publication from

1 2019 that talks about how to prevent ovarian cancer or
2 what preventive action could be taken. Correct?

3 A. Yes.

4 Q. And in this section entitled "Prevention in
5 2019," you make mention of a number of risk factors
6 for ovarian cancer. True?

7 A. These are high risk factors, true.

8 Q. And those risk factors that you included in this
9 80-page Pathways to Progress document states as
10 follows:

11 "Family history and inherited risk are the
12 strongest risk factors for the development of ovarian
13 cancer but they cannot be modified. Obesity is a
14 known risk factor for the development of ovarian and
15 many other cancers."

16 Do you see that?

17 A. Yes.

18 Q. You go on to talk about protective factors for
19 ovarian cancer. Is that correct?

20 A. Yes, and I talked about them earlier today.

21 Q. Mr. Williams reminded me that I did not say the
22 year of this publication, but it was from 2011.
23 Correct?

24 A. Yes.

25 Q. So in 2011, this publication from the Society of

1 Gynecologic Oncology, which mentions prevention of
2 ovarian cancer and risk factors, did not include any
3 discussion of talc as a causative agent for ovarian
4 cancer. Correct?

5 A. That's not shown there, yes.

6 Q. And the purpose or at least the title of this
7 document is "Pathways to Progress in Women's Cancer."
8 Correct?

9 A. It's encouraging us to continue research to
10 find, for example, screening methods, other ways to
11 prevent ovarian cancer, better ways to treat it. It
12 was a comprehensive outline how we would like to
13 progress, and it was intended for many audiences,
14 including the National Cancer Institute that was not
15 funding cancer research adequately in our opinion.

16 Q. We will talk about the NCI a little bit later.
17 In the Pathway to Progress, a Research Agenda Proposed
18 for the Society of Gynecological Oncology, in which
19 your name appears in 2011, this document made no
20 mention that talc causes ovarian cancer. Correct?

21 A. From what you have shown me. I can't recall
22 this whole thing from 2011. You implied I'm the
23 author. I'm not the author of this publication.

24 Q. At this time you were the immediate past
25 president of this Society. Correct, Doctor?

1 A. I was immediate past president. I wasn't the
2 author of this publication.

3 Q. And you authored the cover page of the document
4 that follows. Correct?

5 A. Yes.

6 Q. And you referred to this research report as an
7 effort to outline areas of research in which the
8 women's cancer community should focus for the next
9 decade. Correct?

10 A. We're trying to develop an agenda for a variety
11 of audiences to encourage research, to improve the
12 outcomes of women with ovarian cancer.

13 Q. And you made no mention in your cover letter or
14 in the document itself of talc causing ovarian cancer.
15 Correct?

16 A. And other risk factors, that's true.

17 Q. Now, in 2014, Doctor, you appeared on a Fox News
18 interview. Do you recall that?

19 A. Yes. It was in Greensboro, North Carolina, a
20 very brief morning piece for women that are doing the
21 laundry that lasted about two minutes maybe.

22 Q. And I imagine you were also interested in
23 reaching women who were not doing the laundry. This
24 was an effort to reach all women --

25 A. Anyone who was available at 10 o'clock in the

1 morning, yes.

2 Q. But it was an effort to get the word out about
3 ovarian cancer, for all women, regardless of whether
4 they were folding the laundry at 10 o'clock?

5 A. Exactly. Anybody who was listening, I was happy
6 to have them hear me.

7 Q. I would like to take a look at it and ask you a
8 couple of questions about it, if we could.

9 (The video was played.)

10 Q. Now, Dr. Clarke-Pearson, we can agree, of
11 course, on this television interview, one of the
12 things you were endeavoring to do is to help women.
13 Right?

14 A. Absolutely.

15 Q. You go on in that interview to encourage women,
16 if they think they have signs of ovarian cancer, to go
17 to their doctor and ask to be checked out. Right?

18 A. That's correct.

19 Q. And one of the things you said here is "I hope
20 this clip encourages women to get better care and to
21 detect ovarian cancer earlier." Right?

22 A. Yes.

23 Q. One of the things you did in connection with
24 your effort to help women is you listed some of the
25 risk factors for ovarian cancer. Correct?

1 A. I listed some of the high risk factors, yes.

2 Q. You did not advise the Fox viewers in 2014 that
3 they shouldn't go to the drugstore and buy talcum
4 powder because it causes ovarian cancer. Correct?

5 A. That was not mentioned along with a lot of other
6 things.

7 Q. And the reason you didn't mention that,
8 Dr. Clarke-Pearson, in 2014 is because in 2014 you
9 didn't believe that talc causes ovarian cancer?

10 A. I didn't believe it, but there was certainly
11 mounting evidence that we had to start thinking
12 seriously about that issue.

13 Q. In 2014, Doctor, five years ago, you did not
14 believe the opinions that you've come into this
15 courtroom to give us today. You did not believe that
16 talc causes ovarian cancer?

17 A. I've learned a lot in the last two years.

18 Q. In fact, it wasn't until you became an expert in
19 this litigation that you came to believe that talc
20 causes ovarian cancer. Correct?

21 A. I became an expert after I believed that talc
22 caused ovarian cancer, not the other way around.

23 Q. Well, let's talk a little bit about how you got
24 involved in this litigation.

25 You know one of the plaintiffs' lawyers.

1 Correct?

2 A. Yes.

3 Q. You actually went to medical school with
4 Dr. Thompson. Correct?

5 A. Not true.

6 Q. You were at medical school at the same time.
7 Correct?

8 A. I was a resident in obstetrics and gynecology
9 when Dr. Thompson was a medical student, and I didn't
10 know her at that time.

11 Q. And it was through Dr. Thompson you got involved
12 in this litigation. Correct?

13 A. She asked me if I would evaluate whether I
14 believed talcum powder caused ovarian cancer or not
15 before I started in on my methodologic review of the
16 literature.

17 Q. At the time Dr. Thompson approached you, you had
18 been a practicing gynecologic oncologist for 40 years.
19 Correct?

20 A. Thereabouts, yes.

21 Q. At the time Dr. Thompson approached you, you did
22 not hold the opinion that talcum powder causes ovarian
23 cancer?

24 A. I didn't hold an opinion at that time. That's
25 true.

1 Q. Dr. Thompson approached you in late 2017, early
2 2018. Correct?

3 A. I don't recall exactly when.

4 Q. It wasn't until after you did a review for
5 Dr. Thompson that you came to the opinion that you now
6 hold here today. Correct?

7 A. I did a review for myself. I'm not going to go
8 out and do something for Dr. Thompson because she
9 wants me to say something for her or her firm. I have
10 a reputation, and I feel it's a strong reputation, and
11 I'm not going to sign on as somebody's hired gun. So
12 I reviewed the literature in depth and came to the
13 conclusion talcum powder causes ovarian cancer.

14 Q. You were compensated, of course, to review the
15 literature. Correct?

16 A. After I made a conclusion as to what my position
17 was, yes.

18 Q. And you submitted an invoice for your review of
19 that literature. Correct?

20 A. Yes.

21 Q. And you were compensated by the plaintiffs'
22 lawyers. Right?

23 A. As every expert witness.

24 THE COURT: Did you serve as an expert?

25 THE WITNESS: Witness, not in a product

1 liability, but in many malpractice cases.

2 THE COURT: Not in a case like this before?

3 THE WITNESS: No.

4 BY MS. BROWN:

5 Q. And so if we can work a little bit with timing
6 and this board, Doctor, is it fair to say after
7 Dr. Thompson approached you about being an expert in
8 litigation and you reviewed the literature, you came
9 to the opinion that talcum powder causes ovarian
10 cancer. Correct?

11 A. Yes, after doing a Bradford Hill analysis.

12 Q. And prior to that, though, prior to that time,
13 though, Dr. Clarke-Pearson, you were not of that
14 opinion. Correct?

15 A. I was not of that opinion.

16 Q. I want to talk a little bit about whether or not
17 this opinion that you've come to hold in the last
18 couple of years after getting involved in this
19 litigation, whether that opinion is generally-accepted
20 in your gynecologic community.

21 I want to start by talking about the American
22 College of Obstetrics and Gynecology. You would
23 agree, Dr. Clarke-Pearson, that that is a leading
24 organization in your field. Correct?

25 A. Yes, in obstetrics and gynecology.

1 Q. Nowhere in this paper does it state that talcum
2 powder causes ovarian cancer?

3 A. I would have to look at the words throughout the
4 whole paper and look for cause. I can see what the
5 relative risk is. I could see what the statistical
6 risk is, and it increased significantly.

7 Q. This is one of the six meta-analyses on which
8 you rely. True?

9 A. And all of them showed significant increase risk
10 of ovarian cancer with the use of perineal talc.

11 Q. And this says a causal link has not been
12 established?

13 A. That's in their introduction, yes.

14 Q. What this article says is a mechanism remains
15 unclear. Correct?

16 A. That's what is in their introduction.

17 Q. And another meta-analysis that was done in 2018
18 was the Berge analysis. Correct?

19 A. Yes.

20 Q. And incidentally, Doctor, one of the things your
21 methodology here was to rely on the meta-analyses.
22 Correct?

23 A. In the end, my methodology evaluated all the
24 case-control, cohort and one pooled study, and the
25 meta-analysis. The meta-analysis I feel are more

1 Q. Let's look at literally, a bit at a quick chart,
2 if we could, which is slide 27 of the studies that you
3 cite in your report for the proposition that talc can
4 migrate to the ovaries.

5 We just talked about the Egli Newton 1961
6 study that showed in two people laying down, given
7 drugs for contractions, that carbon particles that
8 have been deposited up near the cervix were found. Is
9 that right?

10 A. The carbon particles got to the tubes and
11 ovaries.

12 Q. This is a real old study. Right, Doctor?

13 A. 1961. It's a while back.

14 Q. I don't even have the '60s on my chart. This
15 two-person carbon particle study was available well
16 before you got involved in this litigation. Correct?

17 A. Yes.

18 Q. Incidentally, Doctor, I want to make sure we are
19 clear on something. Before Dr. Thompson called you
20 and asked you to look at this literature in connection
21 with this lawsuit, this litigation, you were not of
22 the opinion that talc causes ovarian cancer?

23 A. That's what we talked about for a good bit this
24 morning already.

25 Q. I want to make sure we were clear.